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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroynki Morimoto	02500.000006.	3913
5514 7590 05/10/2010 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
05/10/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/647,777

**Applicant(s)**

MORIMOTO ET AL.

**Examiner**

S. TRAN

**Art Unit**

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/14/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While the present specification at page 51 discloses a tableting pressure of  $0.7 \text{ ton/cm}^2$ , it appears that the present specification does not provide adequate support for the tableting pressure of 0.7 to  $1.3 \text{ ton/cm}^2$ .

### ***Response to Arguments***

Applicant's arguments filed 02/12/10 have been fully considered but they are not persuasive.

Applicants indicate at page 2 of the Remarks filed 02/12/10 that *the Examiner acknowledges the specification both enables and describes (i) pressing tablets at  $0.7 \text{ ton/cm}^2$  and (ii) pressing tablets at  $1.3 \text{ ton/cm}^2$ .*

However, to clarify the record, the Examiner only acknowledged that the specification describes pressing tablets at  $0.7 \text{ ton/cm}^2$ . See above 112, first paragraph rejection.

Applicants state that the specification teaches high tableting pressures are deleterious: "when a tablet including granule on which surface a film is coated is produced, the film formed on the surface of the granule isn't destroyed" at page 82, lines 17-19. That is to say, since the film is normally destroyed at high tableting pressure (as explicitly taught at page 6, lines 10-19), those of ordinary skill understand that tableting pressures lower than  $1.3 \text{ ton/cm}^2$  (as shown in Tables 3 and 4) may be utilized without consequence. As to the lower limit of such tableting pressures, Experiment 1 (at specification page 46) shows that  $0.7 \text{ ton/cm}^2$  permits obtaining sufficiently hard tablets. In this regard, since tablets produced at low tableting pressures are normally too soft (as explicitly taught at page 6, lines 8-10), those of ordinary skill in this art understand that higher tableting pressures higher than  $0.7 \text{ ton/cm}^2$  may be utilized as well.

However, in response to applicant's arguments, the examiner notes that Tables 3 and 4 as pointed out by the applicant, still do not provide support for values between  $0.7 \text{ ton/cm}^2$  and  $1.3 \text{ ton/cm}^2$ . Nothing in the teachings at page 6, as pointed out by the applicant, adequately provides support for any values between  $0.7 \text{ ton/cm}^2$  and  $1.3 \text{ ton/cm}^2$ . Accordingly, the 112, first paragraph rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615